UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORKx	
JONATHAN ROBERTS and CHARLES VAVRUSKA,	
Plaintiffs,	
-against-	
MARY T. BASSETT, in her official capacity as Commissioner for NEW YORK STATE DEPARTMENT OF HEALTH; and the DEPARTMENT OF HEALTH AND MENTAL HYGIENE OF THE CITY OF NEW YORK, Defendants.	GG)

CITY DEFENDANT'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR AN ORDER FOR A PRELIMINARY INJUNCTION

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Defendant, the New York City Department of Health and Mental Hygiene ("DOHMH" or "City") by its attorney, GEORGIA M. PESTANA, Corporation Counsel of the City of New York, submits this memorandum of law in opposition to plaintiffs' motion for a preliminary injunction.

PRELIMINARY STATEMENT

On December 27, 2021, the New York State Department of Health issued guidance entitled "COVID-19 Antiviral Treatments Authorized and Severe Shortage of Oral Antiviral and Monoclonal Antibody Treatment Products." Subsequently, on the same day, DOHMH issued a "2021 Health Advisory # 39" which mirrored the State's guidance (collectively, the "Challenged Guidance"). The Challenged Guidance was created to inform hospitals and medical care providers of newly authorized oral antiviral medicines and monoclonal antibody products for the treatment of COVID-19. The Challenged Guidance further established eligibility criteria for use of these treatments in times of supply shortages. One of the criteria set forth in the Challenged Guidance is that a patient have "a medical condition or other factors that increase their risk for severe illness," and that "[n]on-white race or Hispanic/Latino ethnicity should be considered a risk factor, as longstanding systemic health and social inequities have contributed to an increased risk of severe illness and death from COVID-19."Complaint, Exs. A, C.

Plaintiffs are two white males who claim that the Challenged Guidance, particularly the criteria regarding considerations of race when distributing COVID-19 treatments, violates their right to Equal Protection of the law. See Plaintiffs' Memo of Law in Support of their Motion for a

¹ There is a surplus of these treatments in New York City. <u>See</u> Declaration of Dr. Morse, dated February 25, 2022 ("Morse Dec."), ¶ 29.

Preliminary Injunction dated February 18, 2022 ("PI Motion"). As plaintiffs are unable to demonstrate a likelihood of success on the merits of their claim, their application for a preliminary injunction must be denied.

As an initial matter, plaintiffs lack standing. Plaintiffs fail to allege an injury-infact that is concrete and particularized as well as actual or imminent. Indeed, plaintiffs: (1) currently do not have COVID-19; (2) cannot guarantee that they will ever contract COVID-19; and (3) cannot demonstrate that a medical care provider would necessarily treat them with the monoclonal antibody or oral antiviral treatments at issue herein even if they did contract COVID-19.² Additionally and importantly, plaintiffs cannot demonstrate that they are at a substantial risk of harm if they contract COVID-19 because there is no longer a supply shortage of treatments.

Furthermore, plaintiffs fail to demonstrate a likelihood of success on the merits of their equal protection claim. Indeed, the Challenged Guidance satisfies rational basis review as the State and City clearly have an important interest in protecting the public health and the Challenged Guidance suggesting the consideration of race as but one factor in deciding on treatment options, is rationally related to that interest. In the alternative, if this Court applies strict scrutiny, the Challenged Guidance still passes constitutional muster. The Challenged Guidance was issued according to the compelling government interest in remedying discrimination that resulted in members of racial and ethnic minority groups suffering disproportionately from severe effects of COVID-19. The Guidance is narrowly tailored to achieve that interest because it is temporary and

² In fact, new therapeutics recently approved for use in the treatment of COVID-19 may be even more effective than the monoclonal antibody products and oral antivirals at issue herein. <u>See COVID-19 Therapeutics</u>, HHS.gov, https://aspr.hhs.gov/COVID-19/Therapeutics/Pages/default.aspx (last visited Feb. 25, 2022).

flexible, allowing for individualized assessments of patients seeking treatment. Accordingly, plaintiffs' motion for a preliminary injunction should be denied.

LEGAL STANDARD

Plaintiffs fail to satisfy the standards for a preliminary injunction. In order to establish their entitlement to the drastic remedy of a preliminary injunction against government action taken in the public interest, plaintiffs must establish: (1) that they will be irreparably injured if the relief sought is not granted; (2) that they are likely to succeed on the merits of their claims; (3) that a balance of the hardships tips decidedly in their favor; and (4) that an injunction would be in the public interest. See Trump v. Deutsche Bank AG, 943 F.3d 627, 637–640 (2d Cir. 2019); Cent. Rabbinical Cong. of the United States v. NYC Dep't of Health & Mental Hygiene, 763 F.3d 183, 192 (2d. Cir. 2014); Plaza Health Labs., Inc. v. Perales, 878 F.2d 577, 580 (2d Cir. 1989). See also Bery v. City of New York, 97 F.3d 689 (2d Cir. 1996), cert. denied, 520 U.S. 1251 (1997). However, whereas here, the movant seeks to alter the status quo, i.e., to order the State and City to rescind the Challenged Guidance that has been in effect since December 27, 2021, a heightened standard is applicable. When seeking such a mandatory injunction, plaintiffs must show "a 'clear' or 'substantial' likelihood of success." Sunward Electronics, Inc. v. McDonald, 362 F.3d 17, 24 (2d. Cir. 2004), quoting Thomas Doherty Assocs. v. Saban Entm't, Inc., 60 F.3d 27, 34 (2d Cir. 1995).

ARGUMENT

POINT I

PLAINTIFFS LACK STANDING

Plaintiffs claim that they have standing to challenge the State and City Guidance because they have been denied "equal treatment due to their race." PI Motion at 8. Plaintiffs are incorrect.

It is a plaintiff's burden to establish that there is a "case or controversy" between himself and the named defendants in this case. See Warth v. Seldin, 422 U.S. 490, 498 (1975). To establish Article III standing, "a plaintiff must [] allege, and ultimately prove, that he has suffered an injury-in-fact that is fairly traceable to the challenged action of the defendant, and which is likely to be redressed by the requested relief." Baur v. Veneman, 352 F.3d 625, 632 (2d Cir. 2003). A court's jurisdiction cannot be invoked unless the named plaintiff has personally suffered "some threatened or actual injury resulting from the putatively illegal action[.]" Warth, 422 U.S. at 499 (quoting Linda R. S. v. Richard D., 410 U.S. 614, 617 (1973)). See also Manbeck v. Micka, 640 F. Supp. 2d 351, 368 (S.D.N.Y. 2009). "To qualify as a constitutionally sufficient injury-in-fact, the asserted injury must be 'concrete and particularized' as well as 'actual or imminent, not 'conjectural' or hypothetical." Baur, 352 F.3d at 632 quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992).

Plaintiffs assert that "race is the reason that [they] [are] categorically ineligible to receive potentially life-saving COVID-19 treatment under the guidelines." PI Motion at 8. In equal protection cases involving race-based classifications, an injury-in-fact occurs "when the government erects a barrier that makes it more difficult for members of one group to obtain a benefit than it is for members of another group." Northeastern Fla. Chapter of Associated Gen.

Contractors of Am. v. City of Jacksonville, 508 U.S. 656, 666 (1993). "The 'injury in fact' in an equal protection case of this variety is the denial of equal treatment resulting from the imposition of the barrier, not the ultimate inability to obtain the benefit." <u>Id.</u> To establish standing, a plaintiff "need only demonstrate an intent, or that [he] is 'able and ready,' to pursue the benefit." <u>Martinez</u> v. Malloy, 350 F. Supp. 3d 74, 85 (D. Conn. 2018).

Plaintiffs argue that the provisions of the Challenged Guidance that permit considerations of race as one of many factors when determining how to distribute a limited supply of COVID-19 treatments acts as a barrier to plaintiffs (white and non-Hispanic individuals) from obtaining life-saving medicines. PI Motion at 8. Plaintiff Roberts claims that "[g]iven his age, vaccination status, and current health, [he] would be eligible to receive the treatments if only he were non-white or Hispanic." <u>Id.</u> Similarly, plaintiff Vavruska asserts "[a]lthough [he] is eligible for the COVID-19 treatments listed in the directives, he must hope that supplies remain after non-white or Hispanic individuals with the exact same age, vaccination status, and health condition receive them first." <u>Id.</u>

Plaintiffs' claims are misguided. In order to satisfy the standing requirements, plaintiffs must show that the consideration of race as one of many factors in determining the prioritization of the distribution of limited COVID-19 treatment makes it more difficult for white and non-Hispanic individuals to obtain treatments than non-white and Hispanic individuals. See Northeastern Fla., 508 U.S. at 666. That is not the case. Indeed, the Challenged Guidance is just that—guidance. There are no mechanisms in place to track how the City Guidance has been used by providers or to enforce it in any way. Morse Dec., ¶ 27. It is not enforceable by sanctions or

penalties and does not prevent individuals from receiving treatments if they contract COVID-19.³ Individuals who are qualified based on risk factors will not be turned away from necessary treatment based on race. <u>Id.</u> at ¶ 26. Furthermore, the Challenged Guidance is in no way intended to supersede the sound clinical judgment of qualified medical providers. <u>Id.</u> at ¶ 23. Rather, it simply informs hospitals and medical providers that they may take into account race as one of many factors in assessing the prioritization of distribution when there is a limited supply of treatments for COVID-19. Presently, there is no shortage of oral antivirals or monoclonal antibody products in New York City, in fact, there is a surplus. <u>Id.</u> at ¶ 29. Should plaintiffs contract COVID-19 today, they could easily obtain the treatments.

Plaintiffs further claim that "[i]t is of no moment that neither Plaintiff currently has COVID-19 [as] Article III of the U.S. Constitution does not require a showing that an imminent injury is certain, but instead that there is a 'substantial risk that the harm will occur." PI Motion at 9. In support of this assertion, plaintiff Vavruska claims "I engage in activities that subject me to an increased risk of contracting [COVID-19].... I regularly meet with people for work and for socials reasons. ... I want the ability to access any medication that would be beneficial for me to

³ DOHMH's Health Alert Network ("HAN") regularly delivers up-to-date health alert information to medical providers and maintains an online document library on public health topics. Morse Dec., ¶ 22.

⁴ In support of this proposition, plaintiffs cite to <u>Susan B. Anthony List v. Driehaus</u>, 573 U.S. 149, 158 (2014). This case bares little relevance to the instant action. In <u>Susan B. Anthony</u>, the court found that plaintiff advocacy organizations had standing to bring a pre-enforcement challenge to an Ohio statute that criminalized false statements about candidates during political campaigns. <u>Id.</u> at 151–153. Because plaintiffs presented specific proof of intent to engage in such speech, combined with a history of past enforcement, the Court found that plaintiffs could establish a substantial threat of being prosecuted under the statute. <u>Id.</u> at 166. Differently here, plaintiffs have not and cannot present specific proof that they will contract COVID-19 and require oral antivirals or monoclonal antibody treatment. Moreover, there is no history of past enforcement of the Challenged Guidance by the State or the City. Morse Dec., ¶ 27.

take...." <u>See</u> Declaration of Charles Vavruska in Support of Plaintiffs' Motion for a Preliminary Injunction, dated February 18, 2022 (Dkt. No. 19-2), ¶¶ 5, 6. Additionally, plaintiff Roberts claims "I want the ability to access any medication that would be beneficial for me to take. I am especially interested in Paxlovid and have been fascinated by the science of the drug from videos I have watched. I would seek this drug as a possible treatment if I were to contract COVID-19." <u>See</u> Declaration of Jonathan Roberts in Support of Plaintiffs' Motion for a Preliminary Injunction, dated February 17, 2022 (Dkt No. 19-1), ¶ 5. Such speculative and hypothetical scenarios hardly constitute a substantial risk that plaintiffs will be harmed.

Furthermore, plaintiffs cannot demonstrate that that are "able and ready" to "pursue the benefit," i.e., that they are able and ready to pursue oral antivirals and monoclonal antibody products for treatment of COVID-19. Martinez, 350 F. Supp. 3d at 85. Plaintiffs admit that they do not currently have COVID-19, nor can they guarantee that they will ever contract COVID-19 in the future. Furthermore, even if Plaintiffs did contract COVID-19, their symptoms may not warrant the use of the oral antiviral therapies and monoclonal antibody products at issue here. In fact, new COVID-19 treatments have recently come on the market. If plaintiffs contract COVID-19 in the future, it is possible that they would choose a different treatment and that a different treatment would be more effective than the ones at issue herein. Finally, if plaintiffs were to contract COVID-19 today, and required the use of oral antivirals or monoclonal antibody treatments, there is no longer a supply shortage of these treatments to warrant adherence to the Challenged Guidance. Morse Dec, ¶28–29.

Accordingly, as plaintiffs lack standing to challenge the State and City Guidance, their motion for a preliminary injunction must be denied.

⁵ <u>See COVID-19 Therapeutics</u>, <u>supra</u> note 2.

POINT II

PLAINTIFFS ARE UNLIKELY TO SUCCEED ON THE MERITS OF THEIR CLAIMS AGAINST THE CITY

A. Plaintiffs are Unlikely to Succeed on the Merits of their Equal Protection Claim

i. The Challenged Guidance Withstands Rational Basis Review

Plaintiffs are not likely to succeed on the merits of their Equal Protection claim as the Challenged Guidance satisfies rational basis review. While Plaintiffs allege that the Challenged Guidance is subject to strict scrutiny review, the Challenged Guidance does not allocate COVID-19 treatment on the basis of race. The Challenged Guidance is merely guidance that suggests risk factors that prescribing physicians may consider, and includes race and ethnicity as one of many factors. As the Challenged Guidance is not a law or policy that classifies on the basis of race, it is subject to rational basis review. See Christa McAuliffe Intermediate Sch. PTO, Inc. v. De Blasio, 364 F. Supp. 3d 253, 276–277 (S.D.N.Y. 2019).

A government action subject to rational basis review is afforded "a strong presumption of validity," Heller v. Doe, 509 U.S. 312, 319 (1993), and "must be upheld against [an] equal protection challenge if there is any reasonably conceivable state of facts that could provide a rational basis" for it. F.C.C. v. Beach Communications, Inc., 508 U.S. 307, 313 (1993). The Challenged Guidance withstands rational basis review because it is rationally related to the legitimate government interest. City of New Orleans v. Dukes, 427 U.S. 297, 303 (1976). The DOHMH issued the Challenged Guidance with the knowledge that racial and ethnic minorities suffered severe illness and death from COVID-19 at disproportionate rates to white individuals. Morse Dec., ¶23. Thus, including race and ethnicity as one risk factor for COVID-19 is rationally related to the City's legitimate interests in protecting public health by preventing the most severe

forms of illness and death from COVID-19; ensuring that life-saving treatments be distributed to those at the highest risk; and preventing City hospitals from becoming overburdened. <u>See Clementine Co. LLC v. De Blasio</u>, 2021 U.S. Dist. LEXIS 232058, *39–*40 (S.D.N.Y. Dec. 3, 2021) (finding a compelling government interest in protecting public health, specifically in preventing COVID-19 and preventing an overburdening of the healthcare system).

ii. Even if Strict Scrutiny Applies, the Challenged Guidance Survives Judicial Review

In the event that this Court applies strict scrutiny here, the Challenged Guidance survives because the inclusion of race and ethnicity as a risk factor to consider for the prioritization of treatment for COVID-19 is a lawful measure to remedy past discrimination that has resulted in disparate health outcomes for minority communities during the COVID-19 pandemic. "Although all governmental uses of race are subject to strict scrutiny, not all are invalidated by it." Grutter v. Bollinger, 539 U.S. 306, 326–327 (2003) (emphasis added). That a classification is analyzed under strict scrutiny review "says nothing about the ultimate validity of any particular law." Adarand Constructors v. Pena, 515 U.S. 200, 230 (1995). The Supreme Court has recognized that not all government legislation or policy must be race neutral, Fullilove v. Klutznick, 448 U.S. 448, 482 (1980) and in fact, sometimes racial classification is necessary to remedy unlawful discrimination. Richmond v. J. A. Croson Co., 488 U.S. 469, 509 (1989). In order to satisfy strict scrutiny "the government has the burden of proving that racial classifications 'are narrowly tailored measures that further compelling government interests." Johnson v. California, 543 U.S. 499, 505 (2005), quoting Adarand Constructors, 515 U.S. at 227.

a. The Challenged Guidance was Issued to Remedy Past Effects of Discrimination

The Challenged Guidance withstands strict scrutiny as DOHMH issued it ⁶ pursuant to a compelling government interest of remedying effects of discrimination. ⁷ The Supreme Court has found that a government's "interest in remedying the effects of past or present racial discrimination . . . justify a government's use of racial distinction" when (1) the discrimination is identified with some specificity and (2) the entity that makes the racial distinction "had a strong basis in evidence to conclude that remedial action was necessary, before it embark[ed] on an affirmative-action program." Shaw v. Hunt, 517 U.S. 899, 909–910 (1996). It is well established that communities of color face barriers accessing health care, such as lack of insurance, cultural and language barriers, and inequities in treatment that have caused some communities to distrust the government and healthcare system. ⁸ It is also well established that racism and associated chronic stress have had negative biological consequences for Black, Indigenous, Latinx, and other people of color well before COVID-19. Morse Dec., ¶ 24.

Race-neutral policies that have not taken the realities and effects of racism into account have resulted in racial and ethnic minority groups being disproportionately affected by COVID-19. Studies show that when adjusted for age, non-Hispanic American Indian or Alaska

⁶ This section speaks to the City's interests in issuing the Challenged Guidance.

⁷ DOHMH also has a compelling interest in protecting public health, which includes ensuring equal access and distribution of COVID-19 treatments among all New York City communities. See Clementine Co., 2021 U.S. Dist. LEXIS 232058 at *40 (finding there was a compelling interest in preventing the spread of COVID-19 infection to prevent an overburdening of the healthcare system).

⁸See Introduction to COVID-19 Racial and Ethnic Health Disparities, CDC.gov (updated Dec. 10, 2020) https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/index.html.

Native, non-Hispanic Black, and Hispanic or Latinx individuals have higher hospitalization rates compared to non-Hispanic Asian or Pacific Islander and non-Hispanic White people⁹; the percent of Hispanic or Latinx, non-Hispanic Black, and non-Hispanic American Indian or Alaska Native people who have died from COVID-19 is greater than the percent of these racial and ethnic groups among the total United States population¹⁰; and members of certain racial and ethnic minority groups have died from COVID-19 at younger ages compared to non-Hispanic white people.¹¹ Further, a study by Scientific Reports found that, when controlling for medical comorbidities, most racial and ethnic minority groups fared worse than non-Hispanic whites.¹² Controlling for comorbidities, Asian Pacific Islanders and non-Hispanic Blacks had a higher risk for hospitalization, maximum hospital length of stay, invasive ventilator dependence, and death. <u>Id.</u>¹³

Such racial disparities would have been continued by race-neutral policies surrounding the distribution of then limited monoclonal antibody and oral antiviral treatments.

⁹See <u>Disparities in COVID-19-Associated Hospitalizations</u>, CDC.gov (updated Feb. 16, 2022) https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities-hospitalization.html.

¹⁰ <u>See Disparities in Deaths from COVID-19</u>, CDC.gov https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/disparities-deaths.html (last visited Feb. 23, 2022.

¹¹ See Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals, CDC.gov (updated Dec. 10, 2020) https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html#ref_18.

¹² <u>See</u> Fares Qeadan et al., <u>Racial disparities in COVID-19 outcomes exist despite comparable Elixhauser comorbidity indices between Blacks, Hispanics, Native Americans, and Whites, Scientific Reports (Apr. 22, 2021), https://www.nature.com/articles/s41598-021-88308-2.</u>

¹³ Plaintiffs erroneously allege that the rate of death for non-Hispanic white individuals exceeds the rate for any other group in New York. <u>See PI Motion at 1. Plaintiff's own cited source shows that in New York, the distribution of deaths per 100,000 persons is highest for African Americans, then Hispanics, then Asians, and lastly whites. <u>See COVID-19 Health Equity Interactive Dashboard</u>, Emory.edu, https://covid19.emory.edu/36 (last accessed Feb. 24, 2022).</u>

Indeed, DOHMH took into account studies showing that monoclonal antibody treatments had been used less commonly in racial and ethnic minority groups when issuing the Challenged Guidance. CDC data found that "Hispanic patients received mAb 58% less often than did non-Hispanic patients, and Black, Asian, or Other race patients received mAb 22%, 48%, and 47% less often, respectively, than did White patients during November 2020–August 2021." The Supreme Court has explained that a significant statistical showings of racial disparities in accessing a benefit or opportunity—i.e, treatment for COVID-19—can give rise to an inference of discrimination. See Richmond, 488 U.S. at 509; Fullilove, 448 U.S. at 465–466 ("These statistics are not the result of random chance. The presumption must be made that past discriminatory systems have resulted in present economic inequities.").

Further, when such presumptions arise, the Court has found it proper that government entities take appropriate measures to remedy such discrimination. See Fullilove, 448 U.S. at 466; Richmond, 488 at 509. Here, the ample statistics showing the disproportionate impact of COVID-19 on communities of color raise the inference that previous race-neutral COVID-19 programs and policies failed to account for important and well-documented racial disparities, and in doing so, exacerbated racial discrimination. These discrepancies not only raise a presumption of discrimination, but also served as evidence to DOHMH, and presumably the State, that remedial action was necessary. When DOHMH adopted the Challenged Guidance, it was aware that being a member of a racial or ethnic minority group is a well-documented separate risk factor for COVID-19 and that patients in communities of color were accessing monoclonal antibody treatments at significantly lower rates than non-minority patients. Additionally, the CDC and the State had already included race and ethnicity as a risk factor for COVID-19 in their guidance regarding the distribution of monoclonal antibody and oral antiviral treatments. To issue race-

neutral guidance and ignore the evidence of racial disparities would be akin to intentionally maintaining a racially discriminatory policy for distributing live-saving drugs.

b. The Challenged Guidance is Narrowly Tailored to Serve a Compelling Government Interest

The Challenged Guidance is narrowly tailored to remedy past and current discrimination and ensure that racial and ethnic minorities are not at a higher risk for severe or fatal COVID-19. "In determining whether a program is narrowly tailored, [the Second Circuit has] considered: (1) the necessity for relief and the efficacy of alternative remedies, (2) the flexibility and duration of the relief, (3) the relationship of the numerical goals of the relief to the relevant labor market (or to its analog in a case involving something other than employment discrimination), and (4) the impact of the relief on the rights of third parties." Jana-Rock, 438 F.3d at 205–206 (internal citations omitted).

The Challenged Guidance allows for, and in fact requires, individualized assessments of patients who have tested positive for COVID-19 and seek monoclonal antibody and oral antiviral treatments. Prescribing physicians conduct an individualized assessment for each patient and take into account various factors, including age, vaccination status, whether the patient is immunocompromised, and other medical conditions to determine an individual's need for these treatments. See Grutter v. Bollinger, 539 U.S. 306, 337 (2003) ("The importance of the individualized consideration in the context of a race-conscious . . . program is paramount."); Fullilove, 448 U.S. at 460. The Challenged Guidance merely reminds prescribing physicians that they may take into account race and ethnicity as one of many factors in assessing a patient's risk for severe or fatal COVID-19. White patients are not evaluated differently than non-white patients, and race is not a controlling factor in whether a patient is prescribed monoclonal antibody and oral antiviral treatments. See Regents of Univ. Of Cal. v. Bakke, 438 U.S. 265, 317 (1978) (explaining

that an affirmative action program for university admissions that considered race or ethnic background as a "plus" but did not insulate the individual from comparison with other candidates would be constitutional); Grutter, 539 U.S. at 337 (upholding an affirmative action admissions program because it was flexible enough to ensure that each applicant was evaluated as an individual and not in a way that made the applicant's race or ethnicity the defining feature of his or her application).

The Challenged Guidance is also extremely flexible because, as discussed above, it is merely guidance. Prescribing physicians are not bound to follow the Challenged Guidance in circumstances where it does not align with their sound clinical judgment. Indeed, because the Challenged Guidance is not a mandate, the City will not take any enforcement actions against hospitals or medical providers in relation to it, which is evidenced by the lack of enforcement mechanisms currently in place. Morse Dec., ¶ 27. Therefore, a prescribing physician may find that an individual is a good candidate for monoclonal antibody and oral antiviral treatments because of considerations not even mentioned in the Challenged Guidance, such as residing with elderly or immunocompromised family members. See Fullilove, 448 U.S. at 481. The Challenged Guidance was temporary, as it went into effect to address a severe shortage of drugs during a surge in COVID-19 cases as a result of the highly contagious Omicron variant during the height of that surge which has now passed. As discussed above, the City now has a surplus of these medications, and at-risk individuals are not being denied treatment.

Additionally, the Challenged Guidance is a close fit for remedying the disparities of health outcomes and access to treatment within minority communities that have been observed during the COVID-19 pandemic. Studies showed that even controlling for age and medical conditions, race and ethnicity are a separate risk factor for severe COVID-19. Studies also showed

that members of racial and ethnic minority groups were less likely to access antibody treatments.

Appropriately, the Challenged Guidance included race and ethnicity as one risk factor that may be considered in assessing a patient's need for treatment.

Further, as discussed above, the Challenged Guidance in no way harmed Plaintiffs. Neither of the Plaintiffs were infected with COVID-19 while there was a shortage of monoclonal antibody and oral antiviral treatments, and there is currently ample supply of these drugs. Even if Plaintiffs became infected with COVID-19 during the shortage, "[t]he City's Guidance does not prevent any individual from receiving treatments should they contract COVID-19 and no one who is qualified based on risk factors will be turned away from necessary treatment based on race." Morse Dec, ¶ 26.

Finally, Plaintiffs allege that there were "readily available" race-neutral alternatives that would achieve the City's compelling interest. Plaintiffs' suggestion of distributing COVID-19 treatments to those who are more likely to contract COVID-19, such as those who take public transportation, see PI Motion at 15, is inapplicable, because only those who have already tested positive for COVID-19 are eligible for treatment regardless of their mass transit use. As discussed above, a framework that included only race-neutral risk factors such as chronic disease and obesity as also suggested by plaintiffs, see id., would ignore the empirical evidence that race and ethnicity is a separate risk factor for severe COVID-19, and that access to these treatments is lower among communities of color. Thus, a race-neutral approach based solely on medical comorbidities would result in disparities in health outcomes and would not ensure that all high-risk patients had access to live-saving treatments. Additionally, when the Challenged Guidance was issued, the CDC and the State had already included race and ethnicity as a risk factor, so a race-neutral alternative would

have created unnecessary confusion for prescribing physicians within New York City, who were also under the guidance of the State.

POINT III

PLAINTIFFS CANNOT DEMONSTRATE THAT IRREPARABLE HARM IS IMMINENT

As plaintiffs' constitutional claims lack merit, the harm that plaintiffs claim to have incurred as a result of the Challenged Guidance is conclusory and speculative, and as such, insufficient for purposes of satisfying the "irreparable harm" requirement for a preliminary injunction. "Irreparable harm is injury that is neither remote nor speculative, but actual and imminent and that cannot be remedied by an award of monetary damages." New York v. United States Dep't of Homeland Sec., 969 F. 3d 42, 86 (2d Cir. 2020), quoting New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 660 (2d Cir. 2015). As stated above, any alleged injury by plaintiffs at this juncture is purely speculative as neither of them have COVID-19 nor can they guarantee that they will contract it in the future. Regardless, there is no emergency warranting injunctive relief as there is currently a surplus of the very treatments at issue in this action. Morse Dec., ¶ 29. If plaintiffs were to contract COVID-19 today, there is ample supply of oral antivirals and monoclonal antibody products. Accordingly, plaintiffs cannot demonstrate irreparable harm.

POINT IV

A BALANCE OF HARDSHIPS TIPS IN CITY DEFENDANT'S FAVOR.

Plaintiffs seek to enjoin the State's and City's efforts to offer considerations to the medical field about how to distribute various treatments for COVID-19 in times of short supply. Such efforts are clearly in the public interest and serve to promote and protect the health of New

Yorkers. Indeed, there is evidence that "longstanding systemic health and social inequalities have

contributed to an increase risk of severe illness and death from COVID-19," Morse Dec. ¶ 18.

Additionally, studies show that when adjusted for age, non-Hispanic American Indian or Alaska

Native, non-Hispanic Black, and Hispanic or Latinx individuals have higher hospitalization rates

compared with non-Hispanic Asian or Pacific Islander and non-Hispanic White people. 14 The

Challenged Guidance, which is not enforceable, is one mechanism the State and City have

provided to lessen the unequal treatment in the quality of healthcare experienced by minority

groups in New York City.

Accordingly, as plaintiffs have failed to meet any of the requirements for the

issuance of a preliminary injunction, their request for such relief must be denied.

CONCLUSION

For all the reasons set forth herein, City defendant respectfully requests that

Plaintiffs' motion for a preliminary injunction be denied in its entirety.

Dated:

New York, New York

February 25, 2022

By: Samantha Schonfeld /s/

Samantha Schonfeld

Assistant Corporation Counsel

¹⁴See <u>Disparities in COVID-19-Associated Hospitalizations</u>, <u>supra</u> note 9.

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